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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,078	06/02/2005	Donald Keith Martin	FBRIC48.001APC	8640

20995 7590 11/05/2007
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EXAMINER

MARTIN, PAUL C

ART UNIT	PAPER NUMBER
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1657

NOTIFICATION DATE	DELIVERY MODE
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11/05/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartec@kmob.com
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Office Action Summary	Application No. 10/517,078	Applicant(s) MARTIN ET AL.	
	Examiner Paul C. Martin	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 115-131 is/are pending in the application.
- 4a) Of the above claim(s) 1, 115-121 and 128-131 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 122-127 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/6/04 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/11/05, 10/31/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1 and 115-131 are pending in this application.

Election/Restrictions

Applicant's election without traverse of Group III (Claims 122-128) in the reply filed on 01/10/07 and of the species (NSAID: aspirin) in the reply filed 03/06/07 is acknowledged. Claims 1, 115-121 and 128-131 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions and/or species, there being no allowable generic or linking claim. Election was made **without traverse**.

Claims 122-127 were examined on their merits.

Specification

The disclosure is objected to because of the following informalities: The drawings include the following reference character(s) not mentioned in the Brief Description such as letters a-d.

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The use of the trademarks SUPERGLUE™, ARALDITE™, SYLGARD™ and VOLTAREN™ has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. Appropriate correction is required.

Claim Objections

Claim 122 is objected to because of the following informalities: The word "isloated" in line 7 of the claim is a misspelling. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 122 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 122 contains a step of detecting a change in the contractile state of a subject's retinal blood vessels, however the means by which this detection is obtained are unclear. Detection could be through visual identification or by assessment of the electrochemical state of the blood vessel for example.

Claim 126 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 126 contains language wherein the compound is an NSAID, however the phrase "from the group consisting of" appears both in line 3 and 5 of the claim. It is unclear if these are two separate Markush groups or a single grouping. Similarly, there the term derivative is repeated without clear antecedent basis.

Regarding claim 126, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 122-125 are rejected under 35 U.S.C. 102(b) as being anticipated by Bursell *et al.* (1995).

Bursell *et al.* teaches a method wherein a pharmaceutically acceptable amount of ET-1 (endothelin-1), known to cause contraction in isolated bovine retinal vessel segments (Pg. 596, Column 2, Lines 6-11) and activate phospholipase-C (Pg. 596, Column 2, Lines 16-17 and Pg. 597, Column 1, Lines 1-7), is administered to diabetic and non-diabetic rats, detecting a change in the diameters (distortion) of the retinal vessels and comparing the difference between the diabetic and non-diabetic rats wherein a decreased retinal response in the diabetic rats is indicative of impaired retinal blood vessel function due to diabetes (a disease characterized by retinal blood vessel damage) (Pg. 598, Column 1, Lines 6-32 and Lines 50-51 and Column 2, Lines 1-26 and Pg. 602, Table 2 and Pg. 603, Column 2, Lines 1-12).

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The language in Claim 123 relating to the process by which the compound is identified does not materially change the compound and its manner of use in the method, and therefore is not considered a further limitation of the compound of Claim 122.

Claims 122-127 are rejected under 35 U.S.C. 102(b) as being anticipated by Feke *et al.* (1995).

Feke *et al.* teaches a method of diagnosing retinopathy (damage to the retina) in a subject by administering orally the NSAID aspirin to type I diabetic patients with no observable or minimal retinopathy, detecting a change in retinal arterial diameter (distortion) and blood flow and comparing the change in the blood flow and arterial diameters of the diabetic subjects to that of healthy subjects wherein a percent change increase (dilation) in the retinal blood flow and arterial diameters is indicative of impaired retinal blood vessel function (Pg. 110, Column 1, Lines 22-45 and Column 2, Lines 37 and Pg. 113, Column 1, Lines 23-30 and Column 2, Lines 19 and Table 2).

It is inherent in the method of Feke *et al.* that the NSAID aspirin must have the property of producing a change in the contractile state of a blood vessel in an isolated retina, barring any evidence to the contrary.

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Further, the language in Claim 123 relating to the process by which the compound is identified does not materially change the compound and its manner of use in the method, and therefore is not considered a further limitation of the compound of Claim 122. As the compound is orally ingested, the aspirin will contact the subject's eye through the bloodstream.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin
Examiner
Art Unit 1657

10/24/07

/Jon P Weber/
Jon P Weber
Supervisory Patent Examiner 1657